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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICHOLAS A. ROJO

Appeal 2015-005844[1]
Application 11/256,362[2]
Technology Center 3700

Before NINA L. MEDLOCK, KENNETH G. SCHOPFER, and TARA L. HUTCHINGS, *Administrative Patent Judges*.

SCHOPFER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the rejection of claims 8–12, 15–22, and 29–31. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Our decision references the Appeal Brief ("Appeal Br.," filed Dec. 29, 2014) and Reply Brief ("Reply Br.," filed May 15, 2015), and the Examiner's Answer ("Ans.," mailed Mar. 17, 2015) and Final Office Action ("Final Act.," mailed May 8, 2014).

[2] According to Appellant, "[t]he real party in interest is the Nicholas A. Rojo Credit Shelter Trust, with Patricia G. Rojo as the trustee, the owner of U.S. Patent Application No. 11/256,362 through succession from the deceased inventor, Dr. Nicholas Rojo who passed on July 18, 2013." Appeal Br. 4.

We AFFIRM-IN-PART.

BACKGROUND

According to Appellant,

> The present invention relates to implantable systems that include various devices. Examples of such devices include stents, stent grafts, and vascular grafts. The devices contain cells capable of delivering therapeutic agents to a host in need. Such cells are optionally capable of producing and releasing a therapeutic agent in response to changing physiological cues within a host. Such stents and devices may optionally contain port, catheter, and containment envelope systems.

Spec. ¶ 2.

CLAIMS

Claims 8–12, 15–22, and 29–31 are on appeal. Claim 8 is illustrative of the appealed claims and recites:

> 8. A medical device comprising:
>
> an elongated catheter comprising an intravascularly implantable tip end and a port end; and
>
> a porous sac radially disposed about and enclosing said tip end thereby forming a containment envelope between said sac and said tip; said tip having openings or side holes in communication with said containment envelope within said sac; said sac capable of eluting one or more therapeutic agents that elute through said sac in response to a stimulus when biologically active cells for containing one or more therapeutic agents are optionally disposed in said containment envelope.

Appeal Br. 26.

REJECTIONS

1. The Examiner rejects claim 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

2. The Examiner rejects claims 30 and 31 under 35 U.S.C. § 112, second paragraph, as indefinite.
3. The Examiner rejects claims 8, 11, 12, 15, 17–22, 29, and 30 under 35 U.S.C. § 102(e) as anticipated by Herweck.[3]
4. The Examiner rejects claims 8, 9, 11, 12, 15-18 and 22 under 35 U.S.C. § 102(b) as anticipated by Valli.[4]
5. The Examiner rejects claims 8, 10-12, 15-22, and 30 under 35 U.S.C. § 103(a) as unpatentable over Bae[5] in view of Koenig.[6]
6. The Examiner rejects claim 31 under 35 U.S.C. § 103(a) as unpatentable over Valli in view of Herweck or Jacobs.[7]

DISCUSSION

Written Description

With respect to claim 31, the Examiner finds,

> The "sac" having a diameter of "approximately 2-5 mm" lacks original support in that only the stent was originally disclosed as having this diameter; see paragraph [0060] of the present specification. Furthermore the "sac" at this diameter would have to be capable of allowing transfer of nutrients from the surrounding medium to the cells and the "sac" would have to form a containment envelope.

Final Act. 2.

Appellant argues that the Specification either explicitly or implicitly discloses that the sac has a diameter of approximately 2–5 mm because:

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[3] Herweck et al., US 6,955,661 B1, iss. Oct. 18, 2005.
[4] Valli, US 4,437,856, iss. Mar. 20, 1984.
[5] Bae et al., US 5,262,055, iss. Nov. 16, 1993.
[6] Koenig, US 4,084,588, iss. Apr. 18, 1978.
[7] Jacobs, US 3,794,026, iss. Feb. 26, 1974.

> Figure 4 illustrates a stent 11 enclosing a sac 30. The specification states that "[t]he diameter of the collapsed stent can be approximately 2-5 mm." (¶ [0060].) The specification further states that the sac (reservoir) may reside in a stent (¶ [0068]). Therefore, the specification clearly provides support for "the sac having a diameter of approximately 2-5 mm" because the sac can be enclosed within the stent.

Appeal Br. 14.

"Adequate written description means that the applicant, in the specification, must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention.'" *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009) (citation omitted) (brackets in original), *reh'g en banc denied* Sept. 18, 2009. We agree with the Examiner that the Specification does not convey with reasonable clarity that Appellant was in possession of a device as claimed at the time the application was filed because the Specification does not clearly disclose, either explicitly or implicitly, a sac having a diameter of approximately 2–5 mm. The Specification does disclose that the stent has a diameter of approximately 2–5 mm in a collapsed state, and the Specification separately discloses that Figure 4 shows a stent enclosing a sac. *See* Spec. ¶¶ 60, 63. However, we are not aware of any disclosure regarding the dimensions of the stent in its expanded state or whether the stent depicted in Figure 4 is in a collapsed or expanded state. Thus, it is unclear whether the sac in Figure 4 is depicted in relation to a collapsed stent or an expanded stent. For this reason, we agree that the Specification does not support the claimed sac having a diameter of approximately 2–5 mm with reasonable clarity, and we sustain the rejection of claim 31 under 35 U.S.C. § 112, first paragraph.

Indefiniteness

The Examiner finds that claims 30 and 31 are indefinite because the language "'the surrounding medium' lacks antecedent basis and it is unclear whether this limitation refers to the porous sac, the space within the porous sac but outside the cells, or the space outside the porous sac." Final Act. 3. In response to Appellant's arguments, the Examiner proposes that the claim language be amended to read "medium surrounding the sac." Ans. 4. In reply, Appellant indicates that the claim will be amended "as indicated if it is required for allowance." Reply Br. 3. For this reason, we will sustain the rejection of claims 30 and 31 under 35 U.S.C. § 112, second paragraph.

Anticipation: Herweck

With respect to independent claims 8 and 30, the Examiner finds that Herweck discloses a catheter and porous sac as claimed, and more specifically, the Examiner finds that "the tip end as claimed is the portion of the catheter touching extensible member (12) (it has to have side holes in it as required by the present claim language)." Final Act. 4 (citing Herweck Figs. 1, 2, 12; col. 7, ll. 30–54; col. 14, ll. 25–57). The Examiner also finds that "the tip end includes side holes so it is not limited to the edge of the catheter, and the claims do not require that the entire tip end including the edge [is enclosed by a porous sac]." Final Act. 9.

We are persuaded of reversible error by Appellant's argument that the rejection relies on an unreasonably broad interpretation of the claim. Specifically, we agree with Appellant that the broadest reasonable interpretation of the claim consistent with the Specification requires that the most distal portion, or end, of the catheter is surrounded by the porous sac. Appeal Br. 16–18. We agree that the plain meaning of the words in the

claim would indicate that the distal-most edge of the catheter is enclosed by the porous sac, and this interpretation is consistent with the Specification, which only depicts the porous sac enclosing the distal edge of the catheter. *See* Figs. 7–9. Because the Examiner erred in interpreting the claim and because Herweck clearly does not disclose a sac enclosing the distal-most portion of the catheter (*see* Herweck Figs. 1, 2, 12), we do not sustain the rejection of claims 8, 11, 12, 15, 17–22, 29, and 30 as anticipated by Herweck.

Anticipation: Valli

The Examiner relies on the same erroneous interpretation of the claims in finding that Valli anticipates claims 8, 9, 11, 12, 15–18, and 22. Final Act. 5–6, 9–10 (citing Valli Fig. 1; Abstract). For the reasons discussed above and because Valli clearly does not disclose a sac enclosing the distal-most portion of the catheter (*see* Valli Figs. 1–4), we do not sustain the rejection of claims 8, 9, 11, 12, 15–18, and 22 as anticipated by Valli.

Obviousness: Bae and Koenig

With respect to independent claims 8 and 30, the Examiner finds, *inter alia*,

> Bae et al meets the claim language where the catheter as claimed is the tubing (13) and of Bae et al, the tip end as claimed is the [] portion of needle (27) within the device (20) (see Figure 7 and column 5, lines 14 et seq.), the port end as claimed is the syringe end adjacent piston (29), the porous sac as claimed is the pouch (10), and the biologically active cells as claimed are the islets (15) that are tissue cells of islets of Langerhaus (see column 2, lines 1-8).

Final Act. 6.

We are persuaded of error in the rejection at least because we agree with Appellant that the Examiner has not shown the alleged porous sac 10 of Bae is disposed about and encloses the tip end of the needle 27. Appeal Br. 22; *see also* Bae Figs. 7. In fact, the rejection does not specifically address this claim requirement and we see no indication in the rejection or Bae's disclosure persuading us that such would have been obvious. We also see no indication that Koenig addresses this deficiency. Accordingly, we do not sustain the rejection of claims 8, 10–12, 15–22, and 30 over Bae in view of Koenig.

Obviousness: Valli and Herweck or Jacobs

Claim 31 is directed to a medical device including a catheter and a porous sac "radially disposed and enveloping the intravascular tip end" of the catheter. This claim requirement is substantially the same as the limitations of claim 8 addressed above, and the Examiner relies on the same findings with respect to Valli addressed above. We are persuaded that the Examiner erred in rejecting claim 31 for the reasons discussed previously, i.e. that the Examiner has relied on an unreasonably broad interpretation of the claims. Thus, we do not sustain the rejection of claim 31.

CONCLUSION

For the reasons set forth above, we conclude as follows.

We AFFIRM the rejection of claim 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

We AFFIRM the rejection of claims 30 and 31 under 35 U.S.C. § 112, second paragraph, as indefinite.

We REVERSE the rejection of claims 8, 11, 12, 15, 17–22, 29, and 30 under 35 U.S.C. § 102(e) as anticipated by Herweck.

We REVERSE the rejection of claims 8, 9, 11, 12, 15-18 and 22 under 35 U.S.C. § 102(b) as anticipated by Valli.

We REVERSE the rejection of claims 8, 10-12, 15-22, and 30 under 35 U.S.C. § 103(a) as unpatentable over Bae in view of Koenig.

We REVERSE the rejection of claim 31 under 35 U.S.C. § 103(a) as unpatentable over Valli in view of Herweck or Jacobs.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART